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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,178	05/06/2004	Roy H. Hammerstedt	2034-044072	7502
28289	7590	05/04/2005	EXAMINER	
THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			REDDING, DAVID A	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/840,178	<b>Applicant(s)</b> HAMMERSTEDT, ROY H.	
	<b>Examiner</b> David A. Redding	<b>Art Unit</b> 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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## **DETAILED ACTION**

### ***Specification***

The amendment filed 9/22/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: all inclusions of "an integral sensor device can be sealed into the seam of a blood bag or seam of another type of primary container" and the additions of figures 4a and 5a.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-26,28,36,37,38 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,315,767 B1 (Dumont et al.).

Dumont et al. disclose a cell storage and maintenance device which comprises a biosensor (30), a separation barrier consisting of a gated pore membrane (18) and a sensor compartment located between the wall (20) of the container and the membrane (18).

Dumont et al. disclose that the gated pore membrane used in the device is fully disclosed in U.S. patent 5,261,870 (Hammerstedt et al.) which discloses that the membrane pores are occluded with a cellulosic material. Dumont et al. disclose the gated pore to be occluded by an erodible substance sensitive to pH or solvent concentration (see "Summary" section). Further, Dumont et al. disclose that the sensor shows a visually detectable change in the container (ol.4, lines 31-50). An observer using visual observation of the change in sensor appearance is considered to constitute "remote external sensing". Also, blood bags (col.3, lines 57-67) are considered to be aseptic.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 29,30,32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,315,767 B1 in view of USP 5,194,393 (Hugle et al.).

Dumont et al. does not disclose the specifics of the chemical sensor (30). The Hugl et al. patent discloses optical biosensors which rely on fluorescent receptor complexes using one or two receptor molecules (see summary of the invention). Accordingly, it would have been obvious to one skilled in the art to provide the chemical sensor in Dumont et al. with the fluorescent detection complex disclosed in Hugl et al. in view of their known use in optical sensors.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,315,767 in view of U.S. patent 5,814,449 (Schultz et al.).

The patent to Schultz e al. disclose an optical sensor which uses fluorochrome-receptor complex chemistry (co.3, lines 1-67). Accordingly, it would have been obvious to one skilled in the art to provide the chemical sensor in Dumont et al. with the fluorochrome detection complex disclosed in Schultz et al. in view of their known use in optical sensors.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,315,767 B1 in view of USP (Jeffrey et al.).


Jeffrey et al. disclose the use of an optical sensor positioned against an opaque wall (col.3, lines 9-42) for detection of a change in the container from the outside of the container. It would have been obvious to one skilled in the art to replace the chemical sensor in Dumont et al. with the optical sensor with opaque substrate in Jeffrey et al. in view of their known use in devices for monitoring biological materials.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-9178. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David A Redding  
Primary Examiner  
Art Unit 1744

DAR